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DLA PIPER

December 30, 2020

VIA ECF
Honorable Mary Kay Vyskocil
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: ***Pfizer Inc. v. U.S. Department of Health and Human Services et al.***
Case No.: 20-cv-04920-MKV

Dear Judge Vyskocil:

Plaintiff Pfizer Inc. ("Pfizer") files this letter to address two recently issued authorities referenced for the first time in the government's Reply Memorandum of Law, ECF No. 57 (filed Dec. 21, 2020) ("Gov't Reply"). In its Reply, the government makes extensive citation to a newly issued district court opinion in *United States v. Regeneron Pharma., Inc.*, No. 20 Civ. 11217, 2020 WL 7130004 (D. Mass. Dec. 4, 2020) (*see* Gov't Reply 7, 14 & n.3), as well as to a regulation promulgated by OIG that establishes new safe harbors for value-based arrangements, 85 Fed. Reg. 77684 (Dec. 2, 2020), (*see* Gov't Reply 10-11). As these authorities only issued earlier this month, they were not raised in the government's principal brief, and thus Pfizer has not previously had an opportunity to address the government's reliance on them. Pfizer respectfully submits this short letter so that the Court has the benefit of both parties' briefing on these supplemental authorities.

First, the government's reliance on the decision in *Regeneron* is misplaced. As an initial matter, that decision denied a motion to dismiss a filed civil enforcement action, which is a wholly different procedural posture than that presented here. Pfizer's Advisory Opinion Request sought a prospective determination regarding the lawfulness under the AKS of its proposed Programs based on specific, certified facts—in accordance with the advisory opinion process Congress established by statute. *See* 42 U.S.C. § 1320a-7d(b). Pfizer asks this Court to set aside OIG's negative advisory opinion and to issue a declaration of legal rights based on those same certified facts. The Court does not need to contend with contested factual allegations as in *Regeneron* or to consider some other hypothetical fact pattern that might later exist, as the government asserts in its Reply.

Moreover, the government mischaracterizes the *Regeneron* decision as rejecting Pfizer's well-founded contention that an AKS offense requires an improper purpose. (Gov't Reply at 6-7). To the contrary, the court in *Regeneron* repeatedly stated that, in order to establish an AKS violation, a defendant must have "improper intent" to "impermissibly influence patients' drug choice" and stressed that the complaint in that case plausibly alleged that "the expectation of copay assistance . . . *did* change prescriber behavior" because patients (and their doctors) had other pharmaceutical options from

which to choose. 2020 WL 7130004, at *11-13; *see also id*. at *8 (finding that "the heartland of what the AKS is intended to prevent [is] the use of payments to *improperly* influence decisions on the provision of heath care" paid by federal health care programs) (quoting *Guilfoile v. Shields*, 913 F.3d 178, 192-93 (1st Cir. 2019) (emphasis added)). Specifically, those allegations included that the copay assistance program steered physicians and patients away from an option substantially less expensive than Regeneron's product. *Id.* at *2. In those circumstances, the court concluded that the "difficult factual determination" of whether the company had the requisite improper intent could not be decided on the pleadings. *Id.* at *12. By contrast, this Court need not make such difficult determinations. Under the unique facts surrounding tafamidis and Pfizer's proposed Programs, the copay assistance would not improperly induce prescriptions but simply would make it possible for patients to afford the one drug approved by FDA and prescribed by their doctors for their objectively diagnosed, debilitating condition. The government's reliance on the denial of the motion to dismiss in *Regeneron* is therefore unavailing.

Second, the government relies on its own newly-issued regulations establishing and modifying certain AKS safe harbors to claim that Pfizer cannot seek pre-enforcement review of its proposed Programs because the applicability of the AKS "should be determined based on the totality of the facts and circumstances." (Gov't Reply at 11 (citing HHS OIG Final Rule, 85 Fed. Reg. 77684, 77685 (Dec. 2. 2020))). In selectively quoting OIG's new regulation, the government ignores other portions of the same regulation that undermine its jurisdictional and substantive arguments. Nothing about this regulation suggests that the AKS is ill-suited to pre-enforcement review; if anything, the regulation underscores the importance of prospective evaluation of proposed programs based on their particular facts and circumstances to avoid over-regulation and chilling of beneficial arrangements. *See id.* at 77684. Moreover, the sentences directly preceding those quoted by the government refute its claim that the AKS necessarily prohibits financial arrangements that do not fit within a safe harbor established by statute or regulation. *Id.* at 77685 (recognizing that not all "beneficial arrangements" will "fit in these or other available safe harbors," and that "[a]rrangements are not necessarily unlawful because they do not fit in a safe harbor").

Further, and perhaps most consequentially, the new regulation's description of the AKS supports Pfizer's argument that the statute requires an improper quid pro quo, as it explicitly states that the AKS "is an intent-based, criminal statute that prohibits intentional payments . . . *in exchange for* referrals or other Federal health care program business." *Id.* at 77684 (emphasis added). Contrary to the government's inaccurate assertion that Pfizer lacks recent authority to show the AKS requires a corrupting quid pro quo (*see* Gov't Reply at 3), OIG's own regulation itself describes this essential relationship between the offered remuneration and the sought referral or purchase—a conclusion apparent from the AKS's text, title, structure, and purpose, *see Skilling v. United States*, 561 U.S. 358, 412-13 (2010). As Pfizer has explained, providing copay assistance to allow patients properly diagnosed with ATTR-CM to afford the only FDA-approved treatment for that fatal disease cannot be described as a payment "in exchange for" federal health care program business—it is assistance to allow the patient to receive appropriate and necessary medical care and benefits to which they are indisputably entitled.

Undersigned counsel conferred with counsel for the government regarding the filing of this letter, and the government stated as follows: "The Government takes no position but notes that the authorities which Pfizer now wishes to discuss in more briefing were issued before Pfizer filed its Opposition and Reply memorandum, and could therefore have been addressed therein. The Government reserves its right to seek leave to file a letter addressing any arguments raised in Pfizer's letter."

Sincerely,

/s/ Joan McPhee

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